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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,871	09/18/2003	Jean-Pascal Zambaux	2771-657	6762

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INTELLECTUAL PROPERTY / TECHNOLOGY LAW  
PO BOX 14329  
RESEARCH TRIANGLE PARK, NC 27709

EXAMINER
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DEAK, LESLIE R

ART UNIT	PAPER NUMBER
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3761

MAIL DATE	DELIVERY MODE
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11/02/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

88

<b>Office Action Summary</b>	<b>Application No.</b> 10/665,871	<b>Applicant(s)</b> ZAMBAUX, JEAN-PASCAL	
	<b>Examiner</b> Leslie R. Deak	<b>Art Unit</b> 3761	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 August 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 9-63 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9-62 is/are allowed.
- 6) ☒ Claim(s) 63 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claim 63 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,122,129 to Olson et al in view of US 6,391,014 to Silverman.

In the specification and figures, Olson discloses the apparatus substantially claimed by applicant. In particular, Olson discloses a sampler device designed to preserve the integrity of the sample collected. The apparatus comprises a needle-shaped hollow connector or delivery tube 20 that passes fluids therethrough, an inlet end 13 and an outlet end 21, wherein the inlet end 13 may comprise a threaded connector 19 that connects to container 33 via tube 36 (see FIGS 1, 2, 4, column 6). The outlet end 21 has an aperture to allow fluids to exit into container 23 (see column 7, lines 1-35). The connector comprises a membrane or drip boot 22 (see FIG 4). Absent the disclosure that the drip boot or membrane comprises a vacuum, there is gas inherently contained within the membrane. Furthermore, Olson teaches that the entire assembly is sterile (see column 1, lines 5-12, column 2, lines 20-25) to prevent contamination of the sample obtained through the connector 21, indicating that the gas within the membrane is sterile. With regard to applicant's recitation of the 95% sterility of the gas within the membrane, it has been held that where the general conditions of a

Art Unit: 3761

claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See MPEP 2144.05(II)(A). It is the position of the Examiner that Olson's recitation of a "sterile" connection suggests a high degree of sterility, and it is within the skill of a worker in the art to arrive at applicant's claimed sterility level through routine experimentation.

Applicant further claims that the connector comprises **one of** i) a particular pressure of the gas in the membrane; ii) a partial slit in the membrane. the connector and the container.

Olson fails to disclose a membrane with a partial slit through the interior thereof. Silverman discloses a container with a diaphragm with a partial slit therethrough (see FIGS 8a-d) to provide diaphragm integrity while maintaining operator safety and optimize needle and diaphragm versatility (see column 6, lines 5-17). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the membrane disclosed by Olson with a partial slit as disclosed by Silverman in order to maintain diaphragm integrity while maximizing operator safety, as taught by Silverman.

In the alternative to the unpatentably obvious combination of Olson and Silverman with regard to item (ii) in claim 63, it is the position of the Examiner that the limitation in element (i) in claim 63 is also unpatentable. With regard to applicant's recitation of the specific pressure of the gas in the chamber, such as "greater than about 1 atm," it is the position of the Examiner that "greater than about" 1 atm may include 1 atm, since "about 1atm" may include 0.9 atm. Furthermore, due to daily barometric

Art Unit: 3761

fluctuations in atmospheric pressure, a membrane filled with gas at 1 atm on a day with low barometric pressure may increase to "greater than about 1 atm" on a day with high barometric pressure. As such, the Olson device meets the limitation of the claim.

***Allowable Subject Matter***

3. Claims 9-62 are allowed.

4. The following is an examiner's statement of reasons for allowance: The prior art failed to disclose or suggest the device and method claimed by applicant. The subject matter not found was the apparatus or method drawn to an apparatus and its use wherein the apparatus comprises a connector covered by a membrane with a gas contained therein wherein the gas comprises a sufficient pressure to generate a laminar flow along the connector when the connector pierces the membrane, along with the other steps and limitations of the claims.

The prior art of record, US 5,122,129 to Olson, teaches a connector with a piercing element covered by a membrane, but fails to disclose or suggest that the membrane contains a gas with a pressure sufficient to generate a laminar flow when the membrane is pierced. US 6,391,014 to Silverman teaches a connector apparatus with a membrane comprising a slit that does not penetrate completely through the membrane, but does not teach sterility or laminar flow of gas upon connection. Accordingly, the instantly claimed invention is patentable over the prior art of record.

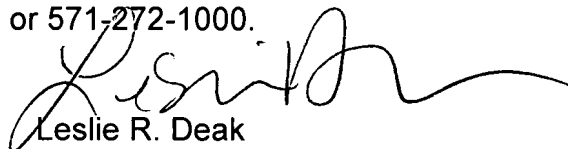
Art Unit: 3761

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Leslie R. Deak  
Patent Examiner  
Art Unit 3761  
25 October 2007